UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte KHALID MENTAK

Appeal No. 2005-2391
Application No. 09/917,971

ON BRIEF

Before HANLON, OWENS, and KRATZ, Administrative Patent Judges.
HANLON, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on an appeal under 35 U.S.C. § 134 from the final rejection of claims 33 through 37, all of the claims pending in the application. The claims on appeal are directed to a method of manufacturing an intraocular lens. Claim 33 is representative and reads as follows:

33. A method of manufacturing an intraocular lens, the method comprising:

a) providing a rigid, hydratable copolymer comprising
a first monomeric component which comprises an aryl acrylate or an aryl methacrylate;

a second monomeric component which comprises a monomer having an aromatic ring with a substituent having at least one site of ethylenic unsaturation, wherein the second monomeric component is other than an acrylate; and
a third monomeric component which comprises a high water content hydrogel-forming monomer,
wherein the copolymer has a glass transition temperature greater than about normal room temperature;

b) forming a rigid intraocular lens having the desired dimensions from the rigid copolymer; and

c) hydrating the copolymer to form a foldable, hydrated intraocular lens,
wherein the hydrated intraocular lens has an equilibrium water concentration less than about 10 weight percent, and a refractive index greater than about 1.55.

The examiner relies on the following references:

Stoy	4,731,079	Mar. 15, 1988
Chromecek et al. (Chromecek)	4,962,170	Oct. 9, 1990
Byerley et al. (Byerley)	5,453,530	Sep. 26, 1995

The following rejections are at issue in this appeal:

(1) Claims 33, 34 and 37 are rejected under 35 U.S.C. § 102(b) as anticipated by Stoy.

(2) Claim 35 is rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Stoy.

(3) Claim 36 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Stoy.

Discussion

A. Rejection of claims 33, 34 and 37

Claims 33, 34 and 37 are rejected under 35 U.S.C. § 102(b) as anticipated by Stoy. The prima facie case of unpatentability is set forth on pages 3 through 5 of the Examiner's Answer. See also Office Action mailed on August 19, 2002, at 2-3.

Specifically, the examiner maintains that the intraocular lens described in Example II of Stoy anticipates the claimed invention. The lens is formed of a hydratable copolymer comprising benzyl acrylate (a first monomeric component), styrene (a second monomeric component) and tetraethyleneglycol-bis-methacrylate (a third monomeric component). Answer at 4.

1. Claims 33 and 37

With respect to claim 33, the sole dispute in this appeal is whether tetraethyleneglycol-bis-methacrylate, i.e., tetraethylene glycol dimethacrylate (TEGDMA), is "a high water content hydrogel-forming monomer." See Brief at 6-10.

The appellant argues that "a high water content hydrogel-forming monomer" within the meaning of claim 33 is a monomer which forms a hydrogel in the homopolymer state. For support, the appellant relies on page 1, lines 27-29 of the specification. Brief at 7. The appellant argues that tetraethylene glycol dimethacrylate is not a hydrogel-forming

monomer because it does not form a hydrogel in the homopolymer state. For support, the appellant relies on a declaration of Khalid Mentak dated November 21, 2003. Brief at 8-10.

The examiner, on the other hand, argues that the specification does not limit "a high water content hydrogel-forming monomer" to a monomer which forms a hydrogel in the homopolymer state. Rather, the examiner argues that the limitation is broad enough to encompass monomers which form hydrogels either in the homopolymer state or when polymerized with other monomers. The examiner relies on the teachings of Stoy, Byerley and Chromecek to establish that tetraethylene glycol dimethacrylate forms a hydrogel when it is polymerized with other monomers.[1] See, e.g., Byerley at col. 9, lines 26-40. The examiner concludes that tetraethylene glycol dimethacrylate is a hydrogel-forming monomer within the meaning of claim 33. See Answer at 7.

An examination of the specification reveals that "a high water content hydrogel-forming monomer" is not limited to a monomer which forms a hydrogel in the homopolymer state. See In re Prater, 415 F.2d 1393, 1404, 162 USPQ 541, 550 (CCPA 1969) (claims are not read in a vacuum but rather must be read in the light of the specification). The passage relied on by the appellant does not discuss hydrogel-forming monomers but merely states that "[h]ydrogel materials are hard or rigid when dry, and

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[1] Although not included in the statement of the rejection, the examiner relies on the teachings of Byerley and Chromecek to establish that tetraethylene glycol dimethacrylate is inherently a hydrogel forming monomer. See Continental Can Co. USA Inc. v. Monsanto Co., 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) ("To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence.").

absorb a large amount of water (e.g., up to 20-70% by weight) when hydrated, which lowers the refractive index of the material [emphasis added]." Specification at 1, lines 27-29. Furthermore, the hydrogel materials are not limited to homopolymers. Therefore, we agree with the examiner that the limitation, when read in light of the specification, encompasses monomers which form hydrogels either in the homopolymer state or when polymerized with other monomers.

There appears to be no dispute that tetraethylene glycol dimethacrylate forms a hydrogel when it is polymerized with other monomers. See Declaration of Khalid Mentak dated November 21, 2003, at 4-5, para. 14 ("ethylene glycol dimethacrylate (EGDMA) . . . and tetra ethylene glycol dimethacrylate (TEGDMA) are commonly polymerized with other hydrophilic monomers to form hydrogels"). Therefore, we agree with the examiner that tetraethylene glycol dimethacrylate is a "high water content hydrogel-forming monomer" within the meaning of claim 33.[2] For this reason, the rejection of claim 33 under 35 U.S.C. § 102(b) as anticipated by Stoy is affirmed.

The appellant argues claims 33 and 37 as a group. Brief at 5. Therefore, the rejection of claim 37 under 35 U.S.C. § 102(b) as anticipated by Stoy is also affirmed.

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[2] The appellant discloses that suitable high water content hydrogel-forming monomers include ethylene glycol dimethacrylate. See Specification at 7, lines 3-4. To the extent that ethylene glycol dimethacrylate forms a hydrogel in the homopolymer state, it is reasonable to expect that tetraethylene glycol dimethacrylate would also form a hydrogel in the homopolymer state. Cf. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) (where the claimed and prior art products are identical or substantially identical, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product).

2. Claim 34

Claim 34 depends from claim 33 and contains the additional limitation that "the rigid intraocular lens and the foldable hydrated intraocular lens differ in volume by less than about 10%." The appellant argues that Stoy does not teach or suggest this limitation. Brief at 10.

With respect to claim 33, the examiner explained that the hydrated lens in Stoy has an equilibrium water concentration of about 10% by weight. The examiner found that "about 10% by weight" satisfies the limitation of "an equilibrium water concentration less than about 10 weight percent" in claim 33. See Answer at 4-5. On appeal, the appellant does not dispute the examiner's finding. Rather, the appellant argues that Stoy does not teach or suggest that the rigid intraocular lens and the foldable hydrated intraocular lens differ in volume by less than about 10%. Brief at 10.

The examiner explains that since the 10% by weight increase is due to water, and the density of water is $1g/cm^3$, the change in volume will be the same as the change in weight. Answer at 10-11. The appellant has failed to establish otherwise. See In re Piasecki, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984) (after a prima facie case of unpatentability has been established, the burden of going forward shifts to the applicant).

We further note that the process for forming an intraocular lens in Example II of Stoy appears to be substantially identical to the claimed method. Therefore, it is

reasonable to expect that the lens formed in Example II of Stoy and the lens formed by the claimed method would have substantially the same properties, such as the volume difference claimed. See In re Best, 562 F.2d at 1255, 195 USPQ at 433 (where the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product).

For the reasons set forth above, the rejection of claim 34 under 35 U.S.C. § 102(b) as anticipated by Stoy is affirmed.

B. Rejection of claim 35

Claim 35 is rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Stoy. Claim 35 is dependent on claim 33 and contains the additional limitation that "the intraocular lens is a 20 diopter lens and has a central thickness less than about 0.4 mm."

The examiner recognizes that the limitation recited in claim 35 is not expressly disclosed in Stoy. Nevertheless, the examiner makes two points in the rejection. First, relying on In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980), the examiner explains that the properties of the lens disclosed in Stoy and the properties of the lens formed by the claimed method would be expected to be the same since the lens

of Stoy and the appellant's lens are made by essentially the same method and are made from essentially the same copolymer. Answer at 5.

Second, the examiner points out that the lens in Example II of Stoy has a central thickness of 0.73 mm at 31.5 diopters. Stoy at col. 14, line 64. The examiner argues that the thickness of the lens at 20 diopters would be very close to the claimed range ((20 x 0.73 mm/31.5) = 0.46 mm). Answer at 5.

The appellant argues that (Brief at 11-12):

> The examiner has failed to consider, however, the effect of the change in thickness to the refractive index of the lens. Claim 33, upon which claim 34 depends, includes the limitation that the lens has a refractive index greater than about 1.55. While Stoy discloses that a lens at 31.5 diopters, and a thickness of 0.73mm has a refractive index of 1.570, it contains no teaching or suggestion that if the diopters are changed to 20 and the thickness to less than 0.4 mm that the refractive index would remain greater than 1.55. Normally such a decrease in thickness leads to a decrease in the refractive index. Therefore if anything, given the teaching of a refractive index of 1.57 of a lens of .73mm thickness, Stoy would suggest that the refractive index of a lens with a thickness 0.4 mm or lower would be less than 1.55.

Significantly, the appellant has failed to provide any evidence to support this argument.[3] See In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965) (arguments in the brief do not take the place of evidence in the record). Therefore, we are not persuaded by the appellant's unsupported allegations.

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[3] We note that the Declaration of Khalid Mentak dated November 21, 2003, does not address the limitations of claim 35 and does not provide factual support for the appellant's arguments with respect to claim 35.

For the reasons set forth above, the rejection of claim 35 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Stoy is affirmed.

C. Rejection of claim 36

Claim 36 is rejected under 35 U.S.C. § 103(a) as unpatentable over Stoy. Claim 36 is dependent on claim 33 and recites specific steps for hydrating the copolymer.

The examiner recognizes that Stoy does not disclose the sequence of hydrating steps recited in claim 36. Nevertheless, the examiner argues that Stoy provides a generic teaching with regard to hydration and concludes that it would have been obvious to one of ordinary skill in the art to utilize any sequence of steps, including the sequence recited in claim 36, with a reasonable expectation of success. Answer at 5-6.

The appellant, on the other hand, argues that Stoy does not teach or suggest any of the steps recited in claim 36 and concludes that Stoy does not render obvious claim 36. Brief at 13-14.

Significantly, Stoy does not disclose the steps recited in claim 36 in ANY sequence. Therefore, absent the appellant's disclosure, there would have been no reason to hydrate the copolymer according to the method recited in claim 36. See In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984) ("The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art

suggested the desirability of the modification."). For this reason, the rejection of claim 36 under 35 U.S.C. § 103(a) as unpatentable over Stoy is reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART; REVERSED-IN-PART

ADRIENE LEPIANE HANLON
Administrative Patent Judge

TERRY J. OWENS
Administrative Patent Judge

PETER F. KRATZ
Administrative Patent Judge

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